

**Notice of Allowability**

Application No.

09/873,403

Examiner

Christopher H. Yaen

Applicant(s)

SRIVASTAVA ET AL.

Art Unit

1643

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/16/2007.
2. ☒ The allowed claim(s) is/are 43-49 and 58-60.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

/Christopher Yaen/  
Primary Examiner  
Art Unit 1643

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Adrian Antler on 8/2/2007.

The application has been amended as follows:

1-42 (Canceled)

43. (Currently Amended): A pharmaceutical composition comprising an amount of a purified molecular complex effective for treatment ~~or inhibition~~ of an infectious disease and a pharmaceutically acceptable carrier, said molecular complex comprising an alpha (2) macroglobulin polypeptide, which comprises the alpha (2) macroglobulin receptor binding domain, said polypeptide noncovalently associated with an antigenic molecule which displays the antigenicity of an antigen of an infectious agent of the infectious disease, with the proviso that the infectious agent is other than hepatitis type B virus.

44. (Previously presented): A purified molecular complex comprising an alpha (2) macroglobulin polypeptide, comprising the alpha (2) macroglobulin receptor binding domain, said polypeptide noncovalently associated with an antigenic molecule that

displays the antigenicity of an antigen of an infectious agent of the infectious disease, with the proviso that the infectious agent is other than hepatitis type B virus.

45. (Previously presented): The purified molecular complex of Claim 43 or 44, wherein the antigenic molecule is an antigen of an infectious agent of the infectious disease.

46. (Currently Amended): The pharmaceutical composition of Claim 43 comprising an amount of a purified molecular complex effective for treatment or inhibition of an infectious disease, wherein the infectious disease is caused by a pathogen of adeno-associated virus, cytomegalovirus, papilloma virus, polyoma viruses, SV40, herpes simplex type I (HSV-I), herpes simplex type II (HSV-II), Epstein-Ban virus, variola (smallpox), vaccinia virus, human immunodeficiency virus type I (HIV-I), human immunodeficiency virus type II (HIV-II), human T-cell lymphotropic virus type I (HTLV-I), human T-cell lymphotropic virus type II (HTLV-II), influenza virus, measles virus, rabies virus, Sendai virus, poliomyelitis virus, coxsackieviruses, rhinoviruses, reoviruses, rubella virus (German measles), Semliki forest virus, arboviruses, hepatitis type A virus, *Streptococcus pyogenes*, *Streptococcus pneumoniae*, *Neisseria gonorrhoea*, *Neisseria meningitidis*, *Corynebacterium diphtheriae*, *Clostridium botulinum*, *Clostridium perfringens*, *Clostridium tetani*, *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Klebsiella ozaenae*, *Klebsiella rhinoscleromatis*, *Staphylococcus aureus*, *Vibrio cholerae*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Campylobacter* (*Vibrio*) *fetus*, *Campylobacter jejuni*, *Aeromonas hydrophila*, *Bacillus cereus*, *Edwardsiella tarda*, *Yersinia enterocolitica*, *Yersinia pestis*, *Yersinia pseudotuberculosis*, *Shigella*

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*dysenteriae, Shigella flexneri, Shigella sonnei, Salmonella typhiimurium, Salmonella typhii, Treponema pallidum, Treponema pertenue, Treponema carateneum, Borrelia vincentii, Borrelia burgdorferi, Leptospira icterohemorrhagiae, Mycobacterium tuberculosis, Toxoplasma gondii, Pneumocystis carinii, Francisella tularensis, Brucella abortus, Brucella suis, Brucella melitensis, Mycoplasma spp., Rickettsia prowazeki, Rickettsia tsutsugumushi, Chlamydia spp., Helicobacter pylori, Entamoeba histolytica, Trichomonas tenax, Trichomonas hominis, Trichomonas vaginalis, Trypanosoma gambiense, Trypanosoma rhodesiense, Trypanosoma cruzi, Leishmania donovani, Leishmania tropica, Leishmania braziliensis, Pneumocystis pneumonia, Plasmodium vivax, Plasmodium falciparum, or Plasmodium malaria.*

47. (Previously presented): A purified population of molecular complexes which are at least 65% noncovalent complexes, each noncovalent complex comprising (i) an alpha (2) macroglobulin polypeptide, which comprises the alpha (2) macroglobulin receptor binding domain, and (ii) an antigenic molecule that displays the antigenicity of an antigen of an infectious agent of the infectious disease, with the proviso that the infectious agent is other than hepatitis type B virus.

48. (Previously presented): The pharmaceutical composition of claim 1 or 43, further comprising one or more adjuvants.

49. (Previously presented): The pharmaceutical composition of claim 48, wherein the adjuvant is aluminum hydroxide, aluminum phosphate, calcium phosphate, lysolecithin, pluronic polyols, polyanions, peptides, oil emulsions, keyhole limpet hemocyanins, and dinitrophenol, cytokines, saponins, muramyl dipeptides, tripeptide

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derivatives, CpG dinucleotides, CpG oligonucleotides, monophosphoryl Lipid A, polyphosphazenes, emulsions, liposomes, virosomes, cochleates, Freund's complete adjuvant, Freund's incomplete adjuvant, bacille Calmette-Guerin, or corynebacterium parvum.

50 - 57. (Canceled)

58. (Previously presented): The pharmaceutical composition of Claim 43, wherein said molecular complex consists essentially of (i) the alpha (2) macroglobulin polypeptide, and (ii) the antigenic molecule.

59. (Previously presented): The purified molecular complex of Claim 44, wherein said molecular complex consists essentially of (i) the alpha (2) macroglobulin polypeptide, and (ii) the antigenic molecule.

60. (Previously presented): The purified population of molecular complexes of Claim 47, wherein said noncovalent complexes consist essentially of (i) the alpha (2) macroglobulin polypeptide, and (ii) the antigenic molecule.

61 - 64. (Canceled)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher Yaen/  
Primary Examiner  
Art Unit 1643  
August 6, 2007